

**CPC Multipurpose Coil****Date of Summary Preparation:** November 20, 2008**JAN 16 2009**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

**1. General Information****Importer/Distributor****Name and Address**

Noras MRI products GmbH  
Leibnizstrasse 4  
97204 Höchberg  
Germany

**Establishment Registration Number**

3004929307

**Manufacturing Site****Name and Address**

Noras MRI products GmbH  
Leibnizstrasse 4  
97204 Höchberg  
Germany

**Establishment Registration Number**

3004929307

Owner/Operator 9071737

## 2. Contact Person

**Zahed Sedighiani**  
Noras MRI products GmbH  
Leibnizstr 4  
97204 Höchberg, Germany

**Telephone:** (+49) 931/29927-17

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**Email Address:** zahed.sedighiani@noras.de

## 3. Device Name and Classification

<b>Trade Name:</b>	Noras CPC – Multifunctional Coil
<b>Common Name:</b>	CPC
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device
<b>Classification Panel:</b>	Radiology
<b>CFR Number:</b>	21 CFR § 892 1000
<b>Device Class:</b>	II
<b>Product Code:</b>	90MOS and LNH

## 4. Device Description

The CPC is a multifunctional coil for 1.5T and 3T MRI-systems, with 2x4-channel phased array receive only coils. The coils are pre-tuned in the factory to the fixed load and no further tuning or matching is required for the user.

The coil is divided into two spherical parts. Each half contains a 4 channel receive only array. The coils were used together with a parallel imaging procedure.

Each coil has its own plug. The plug is specific to the MRI-system and can't be mixed up with a not designated MRI-system.

The base plate is flat and is suitable on each Siemens MRI-system table.

## 5. Intended Use

The intended use of the Noras CPC is, in conjunction with a magnetic resonance scanner, body-imaging for diagnostic with a MRI system

It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of special regions of the human body. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

The application area shouldn't be bigger than 20 cm because of the depth of penetration of 10 cm per coil. The outcome of this is diagnostic images of toes, feet, ankle, knee, finger, hand, wrist, elbow, shoulder, carotid artery, inner ear, baby heart and other parts of the body with similar structure can be taken.

## 6. Substantial Equivalence

Noras believes that, within the meaning of the Safe Medical Devices Act of 1990, the CPC multifunctional coil is substantially equivalent to the following coils.

Coil Name	Premarket Notification	Clearance Date
Machnet Carotids Coil Array Assembly	K 012491	October 24, 2001
Siemens Flex Loop Coil Set 3T	K 063313	November 17, 2006
Invivo Precision Eight Wrist Array Coil 1.5T	K 993477	January 11, 1999
Phased Array Shoulder Coil	K 963356	November 22, 1996
Model 455GE, Phased Array Wrist Coil	K 010074	April 3, 1996
Model CG-WHC18-H150- AP Wrist Hand Coil 1.5T	K 071882	July 18, 2007

## 7. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Devices

The MRI multifunctional CPC coil has been designed to examine the internal structures of special regions of the human body. To get MR images it is mandatory to use the loop coils of the MRT System manufacturer. The approach of this new product was, to give the physician a more comfortable access to the region of interest in the internal structures of special regions of the human body to produce transverse, sagittal, coronal and oblique images, which provide information that can be useful in determining diagnosis.

## 8. General Safety and Effectiveness Concerns

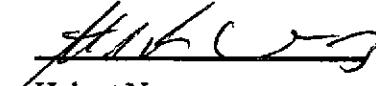
The complete system CPC will conform the harmonized standard of IEC 60601-1 3<sup>rd</sup> edition, Medical electrical equipment - General requirements for basic safety and essential performance

The CPC coil will conform to the FDA recognized NEMA standards for the measurement of performance and safety parameters and the IEC standards for safety issues with the Magnetic Resonance Imaging Devices, IEC 60601-2-33 2003. This will assure that the performance of this device can be considered safe and effective when used with the currently available MAGNETOM systems.

All tests are performed on the Siemens Avanto. This is the most critical engine for safety and performance of the Siemens 1.5T series. Passing these tests gives the Siemens approval for the complete 1.5T series.

## 9. Conclusion as to Substantial Equivalence

Noras believes that, within the definition of the Safe Medical Devices Act of 1990, the Noras multifunctional CPC coils are substantially equivalent to the predicate devices listed above.



Hubert Noras  
President

November 27, 2008



# DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 16 2009

Mr Zahed Sedighian  
Regulatory Affairs Manager  
Noras MRI Products GmbH  
Leibnizstr 4, Hochberg, 97204  
GERMANY

Re K083578

Trade/Device Name CPC  
Regulation Number 21 CFR 892 1000  
Regulation Name Magnetic resonance diagnostic device  
Regulatory Class II  
Product Code MOS  
Dated November 27, 2008  
Received December 3, 2008

Dear Mr Sedighian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to, registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

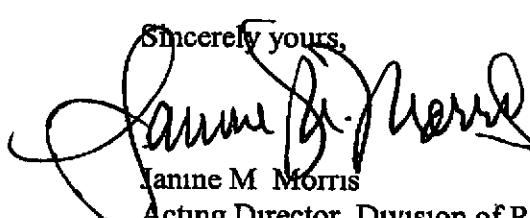
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876 xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884 xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892 xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address [http://www.fda.gov/cdrh/industry\\_support/index.html](http://www.fda.gov/cdrh/industry_support/index.html).

Sincerely yours,



Janine M. Morris

Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Section 2 Indications for use statement

### Indications for Use

510(k) Number (if known) K083578

Device Name CPC

#### Indications for Use

The intended use of the Noras CPC is, in conjunction with a Magnetic Resonance Scanner, Body-imaging for diagnostic with a MRI system

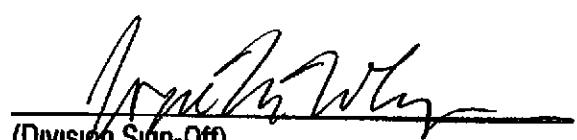
It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of special regions of the human body. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

The application area shouldn't be bigger than 20 cm because of the depth of penetration of 10 cm per coil. The outcome of this is diagnostic images of toes, feet, ankle, knee, finger, hand, wrist, elbow, shoulder, carotid artery, inner ear and other parts of the body with similar structure can be taken.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K083578

(Posted November 13, 2003)